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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,678	11/14/2003	Kenneth Walsh	49784 DIV (71417)	2909

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EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,678	WALSH, KENNETH	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 3-29, drawn to a method for promoting angiogenesis in a tissue of a subject in need thereof, classified in class 514, subclass 460.

II. Claim 2, drawn to a method for treating a subject in need of increased blood flow to a tissue, classified in class 514, subclass 460.

III. Claims 30-41, drawn to a method for activating an Akt polypeptide, classified in class 514, subclass 460.

IV. Claims 42-49, drawn to a method for promoting angiogenesis, classified in class 514, subclass 460.

V. Claims 50-52, drawn to a screening method to identify an Akt activating compound, classified in class 514, subclass 460.

VI. Claims 53-62, drawn to a method for treating a wound, classified in class 514, subclass 460.

The inventions are distinct, each from the other because of the following reasons:

Groups I-VI are directed to methods that are distinct both physically and functionally, and are not required one for the other. The process steps of Groups I and II are similar to each other, but the methods are claimed to be performed on different patient sets (the patient set of Group I is limited, while the patient set of Group II is not). The process steps of Groups III and IV are similar to each other, but these methods do not share end points or starting materials (the cell of Group IV must necessarily undergo

angiogenesis, while the cell of Group III as claimed may be any cell). The method steps of Groups I and II are different from those of Groups III and IV, and all of these steps differ from those of Groups V and VI, which do not share starting materials or end points with each other or any other Group. Therefore, a search and examination of all six methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Conditions: (a) hypertension, (b) diabetic peripheral vascular disease, (c) gangrene, (d) Buerger's syndrome, (e) a wound, (f) ischemia of the muscle, (g) ischemia of the brain, (h) ischemia of the kidney, (i) ischemia of the lung, (k) ischemia of the heart, (l) ischemia of the limb, (m) severe occlusive vascular disease, (n) severe obstructive vascular disease, (o) peripheral vascular disease, (p) myocardial ischemia, (q) myocardial infarction, (r) coronary artery disease, (s) cerebral vascular disease, and (t) visceral vascular disease, as in claim 4, for example.

Statins: (u) lovastatin, (v) pravastatin, (w) simvastatin, (x) fluvastatin, (y) torvastatin and (z) cerivastatin, as in claim 7, for example.

Mode of administration: (a') oral and (b') local, as in claims 8 and 9, for example.

Formulations: (c') salve, (d') gel, (e') film, and (f') patch, as in claim 15, for example.

Growth factors: (g') acidic fibroblast growth factors, (h') basic fibroblast growth factors, (i') vascular endothelial growth factor, (j') epidermal growth factor, (k') transforming growth factor-α, (l') transforming growth factor-β, (m') platelet-derived endothelial cell growth factor, (n') platelet-derived growth factor, (o') tumor necrosis factor-α, (p') hepatocyte growth factor, and (q') insulin like growth factor, as in claim 20, for example.

Akt proteins: (r') Akt-1, (s') Akt-2, and (t') Akt-3, as in claim 24, for example.

Downstream signaling events: (u') phosphorylation of an Akt substrate molecule, (v') a change in the rate of protein degradation, (w') a change in the level of mRNA transcription, (x') a change in the level of protein translation, (y') reduction of apoptosis, and (z') induction of angiogenesis, as in claim 34, for example.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

That is, if Group I is elected, applicant should also choose ONE condition from (a)-(t) above, ONE statin from (u)-(z) above, ONE mode of administration from (a') and (b') above, ONE formulation from (c')-(f') above, ONE growth factor from (g')-(q') above, and ONE Akt protein from (r')-(t') above.

If Group III is elected, applicant should also choose ONE statin from (u)-(z) above, ONE Akt protein from (r')-(t') above, and ONE downstream signaling event from (u')-(z') above.

If Group IV is elected, applicant should also choose ONE statin from (u)-(z) above and ONE Akt protein from (r')-(t') above.

If Group VI is elected, applicant should also choose ONE statin from (u)-(z) above and ONE formulation from (c')-(f') above.

Currently, claims 1, 3-49, and 53-62 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

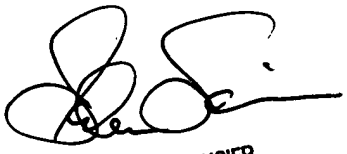
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart, whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn, can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SANDRA E. SAUCIER
PRIMARY EXAMINER

Lora E Barnhart

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